510(k) Summary

K101853

1.0 Submitted By:

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2.0 Date Submitted

June 30, 2010

3.0 Device Name(s):

PLAC® Test Reagent Kit

4.0 Classification

Reagent:
866.5600 Low-density lipoprotein immunological test system
NOE; test, system, immunoassay, lipoprotein-associated phospholipase a2

5.0 Legally Marketed Device

Predicate	Predicate Manufacturer	Docket Number
PLAC® Test ELISA Kit	diaDexus	K062234

6.0 Device Description

The PLAC® Test Reagent Kit consists of separately packaged reagents, calibrators and controls for the measurement of Lp-PLA_2 in serum or plasma on automated clinical chemistry analyzers.

PLAC® Test Reagent Kit

- R1 Buffer solution with protein stabilizers
- R2 Suspension of polymeric microparticles coated with mouse monoclonal antibodies specific to Lp-PLA_2 (2C10 and 4B4).

The PLAC® Test Reagent Kit is based on turbidimetric immunoassay technology utilizing two Lp-PLA_2-specific monoclonal antibodies (2C10 and 4B4) coated to polymeric microparticles. A set of Lp-PLA_2 calibrators is used to plot a standard curve of absorbance (y-axis) versus Lp-PLA_2 concentration in ng/mL (x-axis) from which the Lp-PLA_2 concentration in the test sample can be determined. The concentration of Lp-PLA_2 in each sample and control is then interpolated from the standard curve using a spline curve fit with appropriate calibration curve fitting software. The kit expiration date and storage conditions are indicated on the package.

7.0 Intended Use

REAGENT KIT

The PLAC® Test Reagent Kit is a turbidimetric immunoassay for the quantitative determination of Lp-PLA_2 (lipoprotein-associated phospholipase A_2) in human plasma or serum on automated clinical chemistry analyzers, to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease, and ischemic stroke associated with atherosclerosis.

8.0 Similarities and Differences to the Predicate

Similarities

Item	Predicate – k062234 PLAC Test ELISA Kit	Modified - PLAC Test Reagent Kit
Product Intended Use/Indications	The diaDexus PLAC® Test ELISA Kit is an enzyme immunoassay for the quantitative determination of Lp-PLA_2 (lipoprotein-associated phospholipase A_2) in human plasma and serum, to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease, and ischemic stroke associated with atherosclerosis.	The PLAC® Test Reagent Kit is a turbidimetric immunoassay for the quantitative determination of Lp-PLA_2 (lipoprotein-associated phospholipase A_2) in human plasma or serum on automated clinical chemistry analyzers, to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease, and ischemic stroke associated with atherosclerosis.
Key Reagent Components	Anti-PLA2 (2C10) and anti-PLA2 (4B4)	same
Calibrators Matrix	Recombinant Lp-PLA_2 antigen in a protein stabilizing diluent	Same
Control Matrix	Recombinant Lp-PLA_2 antigen in a protein stabilizing diluent	same
Controls Levels	2	same

Differences

Item	Predicate – k062234 PLAC ELISA Kit	Modified - PLAC Test Reagent Kit
Measuring range	0-1000 ng/mL	25 to 500 ng/mL
Methodology	Dual monoclonal antibody sandwich ELISA read at 450 nm on a microwell plate reader	Immuno- Turbidimetric assay read at 570 nm on clinical chemistry analyzers
Reagent Configuration	• Anti-Lp-PLA_2 mAb (2C10) coated stripwells • Wash buffer • Enzyme conjugate anti-Lp-PLA_2 mAb (4B4)-HRP • TMB substrate • Stop solution	Two reagent system R1- Buffer solution with protein stabilzers R2- antibody coated microparticles (mAbs 2C10 and 4B4)
Kit Configuration	Reagent, calibrators and controls all in one kit	Reagent, calibrators and controls in separate kits.
Calibrator Levels	6 levels - 0,50,100, 250, 500, 1000 ng/ml	5 levels - 0, 50, 100, 250, 500 ng/ml
Reference Range	Median value is 235 ng/ml per population studied in 2006	Median value is 152 ng/mL per population studied in 2010
Samples Types	Serum, EDTA, Heparin	Serum, K_2EDTA

9.0 Summary of Performance Data

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Assay equivalence is demonstrated through method comparison and imprecision studies.

Methods Comparison Data

Predicate Method	Slope	Intercept	R	n	Acceptance Criteria	Modified Product
PLAC® Test ELISA Kit	1.09	-1.7	0.92	742	Slope 0.9 to 1.1 Intercept ≤ 50 ng/mL r ≥0.90	PLAC® Test Reagent Kit

Imprecision Testing

Samples	Mean Concentration Lp-PLA_2 (ng/mL)	Intra-assay %CV n=40	Inter-assay %CV n=40	Total Assay %CV n=80
Serum 1	56.2	2.5%	4.6%	5.3%
Serum 2	250.1	1.0%	2.7%	2.9%
Buffer Control 1	191.2	0.7%	0.9%	1.4%
Buffer Control 2	370.8	1.0%	0.7%	1.6%

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

diaDexus, Inc.
c/o Nina Peled, PhD
Regulatory Affairs Consultant
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South San Francisco, CA 94080

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Re: k101853
Trade/Device Name: PLAC® Test Reagent Kit
Regulation Number: 21 CFR 866.5600
Regulation Name: Low-density lipoprotein immunological test system
Regulatory Class: Class II
Product Code: NOE
Dated: November 23, 2010
Received: November 24, 2010

Dear Dr. Peled,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Indications for Use Form

510(k) Number (if known): K101853

Device Name: ___PLAC® Test Reagent Kit_____

Indications for Use:

The PLAC® Test Reagent Kit is a turbidimetric immunoassay for the quantitative determination of Lp-PLA_2 (lipoprotein-associated phospholipase A_2) in human serum or plasma on automated clinical chemistry analyzers, to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease, and ischemic stroke associated with atherosclerosis.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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